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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,125	12/22/2003	Peter M. Bonutti	2500DV2CN2DV3CN6	7494
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Tyco Healthcare Group LP 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473			EXAMINER	
			KASZTEJNA, MATTHEW JOHN	
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/743,125	<b>Applicant(s)</b> BONUTTI, PETER M.
	<b>Examiner</b> MATTHEW J. KASZTEJNA	<b>Art Unit</b> 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 August 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-15 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-15 and 22-29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2008 has been entered.

### ***Notice of Amendment***

In response to the amendment filed on July 24, 2008, amended claims 11, 25 and 28 are acknowledged. The following new grounds of rejection are set forth:

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6, and 11 of copending Application No. 10/729,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 11 of copending Application No. 10/729,634. Claims 1 and 11 of copending application No. 10/729,634 recite a retractor comprised of a shaft, inflatable bladder disposed at an end of the shaft where the bladder has an inflatable shape selected from the group consisting of circular, oval, eccentric, oblong, conical, wedge-shaped, V-shaped and multiple lobes, along with other features. Claim 11 of the instant application recites a retractor comprised of a shaft and an inflatable bladder that is eccentric or eccentrically mounted on the shaft. Furthermore, claims 13-15 of the instant invention are identical to claims 4-6 of copending Application No. 10/729,634, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7 of copending Application No. 10/743,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claims 1 and 7 of copending Application No. 10/743,192.

The combination of claims 1 and 7 disclose a similar retractor of the instant invention differing only in the shape of the inflatable bladder. Furthermore, claims 13-15 of the instant invention are identical to claims 2-4 of copending Application No. 10/743,192, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-21 of copending Application No. 10/729,768 (Note: Claims 15-21 refer to the most recent claim amendment on file in Application No. 10/729,768 - filed July 1, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application is broader than claim 1 and 21 of copending Application No. 10/729,768. Claim 1 of copending Application No. 10/729,768 recites an apparatus comprised of a shaft and an inflatable bladder wherein the inflatable bladder has a shape selected from the group consisting of: eccentric, conical and wedge-shaped, along with other features. Claims 13-15 are identical to claims 16-18 of copending Application No. 10/729,768, respectively.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15 and 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,071,406 to Jang.

**In regard to claim 11,** Jang discloses a retractor comprising: a shaft 50 including at least one flexible portion (see Col. 4, Lines 67-68); a plurality of inflatable bladders 42, 62, 80 partially circumscribing an outer surface of the shaft (see Figs. 2-5 and Col. 11, Lines 57-60), at least one of the inflatable bladders being disposed adjacent to the at least one flexible portion of the shaft (see Col. 6, Lines 10-25) and being configured to transition from an uninflated state to an inflated state, whereupon the at least one flexible portion of the shaft is rendered rigid upon inflation of the at least one inflatable bladder (see Col. 9, Lines 40-46) and a cannula (i.e. guiding catheter, not shown) having a passage which receives the shaft to deploy the bladder at a target site in tissue (see Col. 1, Lines 30-35 and Col. 4, Lines 64-66).

**In regard to claim 12,** Jang discloses a retractor, wherein the at least one inflatable bladder is shaped so that it expands into an eccentric shape when inflated by fluid pressure introduced through the shaft (see Figs. 3-5 and Col. 11, Lines 40-41).

**In regard to claim 13,** Jang discloses a retractor, wherein the at least one inflatable bladder does not substantially stretch when fully inflated (see Col. 9, Lines 40-42).

**In regard to claims 14-15,** Jang discloses a retractor, wherein the at least one inflatable bladder operates at inflation pressure from 10 mmHG to 1000 mmHG (see Col. 10, Lines 1-6).

**In regard to claims 22 and 26,** Jang discloses a retractor, wherein the plurality of inflatable bladders is eccentrically mounted on the shaft (see Figs. 3-5 and Col. 5, Lines 62-63 and Col. 11, Lines 40-41).

**In regard to claims 23 and 25,** Jang discloses a retractor, wherein the plurality of inflatable bladders includes at least two inflatable bladders that abut each other (see Col. 6, Lines 10-11).

**In regard to claims 24 and 27,** Jang discloses a retractor, wherein the plurality of inflatable bladders is axially spaced along the shaft (see Fig.11).

**In regard to claim 28,** Jang discloses a retractor comprising: a shaft adapted to transition from a first condition (i.e. deflated), in which the shaft 50 includes at least one flexible portion, to a second condition (i.e. inflated), in which the at least one flexible portion is rendered rigid; a plurality of bladders 42, 62, 80 at least partially circumscribing an outer surface of the shaft(see Figs. 2-5 and Col. 11, Lines 57-60), each bladder in the plurality of bladders abutting at least one other bladder (see Col. 6, Lines 10-11) and selectively inflatable for transitioning a portion of the shaft from the first condition to the second condition (see Col. 4, Lines 60-61); and a cannula (i.e. guiding catheter, not shown) having a passage extending therethrough that is configured to receive the shaft (see Col. 1, Lines 30-35 and Col.4, Lines 64-66).

**In regard to claim 29,** Jang discloses a retractor wherein the shaft decreases in flexibility as it transition from the first condition to the second condition (see Col. 9, Lines 39-46). The shaft inherently decreases in flexibility as the non-elastic balloons are inflated.

***Response to Arguments***

Applicant's arguments filed July 24, 2008 have been fully considered but they are not persuasive.

Applicant states that Jang fails to a shaft wherein at least one of the inflatable bladders is disposed about the at least one flexible portion of the shaft and is configured to transition from an uninflated state to an inflated state, whereupon *the at least one flexible portion of the shaft is rendered rigid* upon inflation of the at least one inflatable bladder. Examiner disagrees. As mentioned by the applicant, the catheter shaft 50 must be flexible and resilient to that the catheter can negotiate tortuous and sometimes irregular arteries (see Col.4 -lines 67- Col. 5, Line 3). The catheter is structured as such to enable insertion to a desired site within the body. The balloons are also deflated during insertion of the catheter (see Col. 9, Lines 39-40), which allows for maneuvering through tortuous body cavities. When the catheter is properly positioned inside a lesion 114, the catheter is stationary (thus lacking the need to be flexible), and the appropriate balloon(s) are then inflated to effect treatment of the lesion. Thus, the shaft is rendered rigid upon inflation of the bladders 42, 62, 80 as the catheter is used for the dilation of lesions within arteries (see Fig. 34 and Col. 21, Lines 48-56). As taught by Jang, the hard, non-elastic balloons, when inflated, have the ability to compress sclerotic lesions

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or stretch the narrowed segments in order to increase blood flow through a diseased blood vessel (see Col. 9, Lines 42-46). The shaft, as seen in Figures 3-6, must be *rendered rigid* during inflation of an inflatable bladder, to enable complete dilation of a lesion to be treated within the artery. Thus, as broadly as claimed, Jang meets the limitations of the recited claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./  
Examiner, Art Unit 3739

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